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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/656,849 | 09/05/2003 | Gary Ashe | 1584-6 | 8581 |
| 44190 | 7590 | 12/16/2005 | EXAMINER | |
| WALTER W. DUFT LAW OFFICES OF WALTER W. DUFT 8616 MAIN ST SUITE 2 WILLIAMSVILLE, NY 14221 | | | HAND, MELANIE JO | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3761 | |
| DATE MAILED: 12/16/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/656,849 | | ASHE ET AL. | |
| | Examiner | | Art Unit | |
| | Melanie J. Hand | | 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/22/04, 1/26/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statements

The information disclosure statements (IDS) submitted on January 22, 2004 and January 26, 2004 were filed after the mailing date of the Application on September 5, 2003. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

The disclosure is objected to because of the following informalities: the word "fome" present in the title is misspelled.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Severin et al (U.S. Patent No. 6,488,665) in view of D'Alessio (U.S. Patent No. 6,595,940)

With respect to **Claims 1,11**: Severin teaches a skin preparation delivery system 10 comprised of container 14 with container opening 20 at one end, said container holding a gel formulation 12, and sponge 28 permanently attached to gel applicator 26. Severin teaches gel applicator head 60 located adjacent the open end of container 14. (Fig. 2) (Col. 6, lines 21, 24-26, 37-41)

Severin does not teach that gel formulation 12 is housed in a hermetically sealed ampule disposed in container 14. D'Alessio teaches an applicator 10 comprising a sealed frangible ampoule 30 that delivers a liquid solution when crushed. D'Alessio teaches that sealing can be "achieved by several sealing methods such as ultrasonic welding and heat bonding" and "are known to the skilled artisan". (Col. 5, lines 55-57,61,62) Since hermetic sealing comprises characteristics of both of these methods, Examiner is concluding that D'Alessio is also teaching hermetic sealing. D'Alessio teaches that sealing a biomedical composition in an ampoule removes the need for

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monitoring and storing in a specific environment and can be dispensed by crushing the ampoule at any time by a user, ('940, Col. 4, lines 24-29), therefore it would be obvious to one of ordinary skill in the art to modify container 14 taught by Severin to contain a hermetically sealed ampule that houses a composition as taught by D'Alessio.

With respect to **Claims 2,3,5,12,13,15**: D'Alessio teaches swabs 50 and 60 comprised of polyurethane foam attached to the end of an applicator body 20. (Col. 6, lines 47,48)

With respect to **Claim 4,14**: D'Alessio teaches that swabs 50 and 60 can be of any suitable shape based on the desired mode of application. (Col. 7, lines 9, 10, 17-20) As can best be seen in Fig. 1, D'Alessio teaches a swab of generally circular cross-section.

With respect to **Claim 6,16**: D'Alessio teaches end 28 of applicator body 20 that comprises a hollow circular mounting surface, considered herein to be equivalent to an annular mounting flange.

With respect to **Claim 7,17**,: Severin teaches that the amount of pressure applied to container 14 and holes 29 in sponge applicator 28 provide flow control of the gel formulation 12 through delivery system 10. (Col. 8, lines 50-53)

With respect to **Claim 8,18**: Severin teaches gel dispenser 16 through which gel released from container 14 flows and is held temporarily until said gel is dispensed through holes 29 in sponge applicator 28. (Fig. 1) (Col. 6, lines 29-36)

With respect to **Claim 9,19**: Severin teaches that gel applicator 26 is slidably connected with container connector 24 and is slidably movable from the non-activated position to the activated position, i.e. from having seal piercing member 30 positioned distally from seal 22 to having it proximate seal 22 in piercing position and subsequently piercing said seal. (Figs. 2-5) (Col. 7, lines 4-10, 15-18, 22-24)

With respect to **Claim 10,20**: Severin teaches that seal piercing member 30 is comprised of seal piercing point 70. (Figs. 2-5) (Col. 8, lines 27,28)

With respect to **Claim 21**: Please see the rejections of Claims 1-10 as all of the limitations set forth in Claim 21 have been addressed in those rejections.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

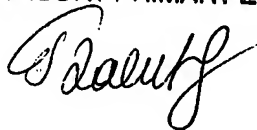
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'T. Zalukaeva', is written over the printed name and title.